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|--------------------------|------------------------|---------------------|--|
| Interview Summary | Application No. | Applicant(s) | |
| | 08/479,997 | ENGELHARDT ET AL. | |
| | Examiner | Art Unit | |
| | Ardin Marschel | 1631 | |

All participants (applicant, applicant's representative, PTO personnel):

(1) Ardin Marschel (Ex)

(3) Ron Fuchs (3pl. Rep.)

(2) Gene Rymando (3pl. Rep.)

(4) Rob. Schulman (3pl. Rep.)

Date of Interview: 12/16/04

(5) Michael Woodward (SPE)

Type: a) Telephonic b) Video Conference
c) Personal [copy given to: 1) applicant 2) applicant's representative]

Exhibit shown or demonstration conducted: d) Yes e) No.
If Yes, brief description: Fix proposed options

Claim(s) discussed: Proposed claim only

Identification of prior art discussed: Hartman et al. [Bipolymers 20: 2635(1981)]

Agreement with respect to the claims f) was reached. g) was not reached. h) N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: We discussed the majority of the met issues to get a met order. We discussed possible claim only to overcome the rejections.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN ONE MONTH FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Ardin Marschel /
Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case. It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
(The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

Greenberg Traurig

Transmittal Cover Sheet

TO Michael P. Woodward
Company USPTO
Fax Number 1-571-273-0722
Phone Number 1-571-272-0722
FROM Eugene C. Rzucidlo
File Number 08/486,070 and 08/479,997
Comments Dear Mr. Woodward:

Attached are proposed agendas for the interview on December 16, 2004. It is hoped that these summaries will be helpful to you and Dr. Marschel.

Thank you.

Gene

Date December 14, 2004
Time
No. Pages Including this cover sheet 5

Please notify us immediately if not received properly at 212.801.9297.

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PROPOSED AGENDA FOR DECEMBER 16, 2004 INTERVIEW

U.S. PATENT APPLICATION SERIAL NO. 08/486,070

1. Purpose of the interview is to reduce or resolve the remaining issues and/or to place the application in allowable condition.
2. Summary of rejections in the November 26, 2004 (non-final) Office Action:

| ISSUE NO. | REJECTION | DESCRIPTION |
|-----------|----------------------------|---|
| 1 | NEW MATTER | "a set of plates", "a set of . . . depressions", or "a set of . . . beads". |
| 2 | NEW MATTER | "more than one surface" |
| 3 | NEW MATTER | "to one" of said reactive sites or binding sites |
| 4 | NEW MATTER | "proportional to" an amount of label |
| 5 | NEW MATTER | quantifiability "in" or "through" a non-porous solid support |
| 6 | NEW MATTER | "iminobiotin," "hapten" or "ligand" limitation |
| 7 | NEW MATTER | "set" limitations |
| 8 | NEW MATTER | "various" nucleic acids |
| 9 | NEW MATTER | array . . . wells or depressions . . . not <i>in situ</i> |
| 10 | VAGUENESS /INDEFINITENES S | metes and bounds of "set comprising the non-porous solid support" |
| 11 | VAGUENESS /INDEFINITENES S | "directly or indirectly fixed or immobilized" |
| 12 | PRIOR ART (ANTICIPATION) | Stuart et al., U.S. Patent No. 4,732,847 |

3. Of the 12 rejections, we have claim proposals for six of the issues (Nos. 1, 3, 5, 7, 10 and 11) as follows:

ISSUE 1: "a set of plates", "a set of . . . depressions", or "a set of . . . beads".
 Claim 3147. (Proposed) The non-porous solid support of claim 3144 or 3145, wherein said non-porous solid support comprises a plate, a well or wells, a microtiter well or microtiter wells, depressions, tubes, cuvettes, beads, or a set an arrangement of said plates, wells, depressions, tubes, cuvettes or beads.

ISSUE 3: "to one of" said reactive sites or binding sites

Claim 3149. (Proposed) The non-porous solid support of claim 3144 or 3145, comprising reactive sites or binding sites thereon, wherein said nucleic acid is fixed or immobilized to one of said reactive sites site or binding sites site.

Enz-7(P)(C3)

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ISSUE 5: quantifiability "in" or "through" a non-porous solid support

Claim 3165. (Proposed) The non-porous solid support of claim 3145, wherein said non-porous solid support is transparent or translucent, and said non-radioactive chemical label is quantifiable in or from a fluid or solution or ~~in or through~~ from said non-porous solid support, said quantity being proportional to the amount or quantity of said label or labels.

ISSUE 7: "set" limitations

Claim 3170. (Proposed) A set comprising an arrangement of the non-porous solid support supports of claim 3144.

ISSUE 10: metes and bounds of "set comprising the non-porous solid support"

Claim 3170. (Proposal) A set comprising an arrangement of the non-porous solid support supports of claim 3144.

ISSUE 11: "directly or indirectly fixed or immobilized"

Claim 3144. (Proposed) A non-porous solid support comprising at least one single-stranded nucleic acid directly or indirectly fixed or directly or indirectly immobilized thereto in hybridizable form, wherein when said nucleic acid is indirectly fixed or indirectly immobilized to said non-porous solid support, said indirect fixation or indirect immobilization is not to a cell fixed *in situ* to said non-porous solid support.

4. On the issue of "various denatured nucleic acids" (Issue No. 8), we would like to discuss the expert's declaration (Dr. Alexander A. Waldrop, III) submitted in the June 30, 2004 Amendment Under 37 C.F.R. §1.116, and his conclusions in Paragraph 14, as supported by his reasons in Paragraphs 15-23 (pages 10-16).

5. With respect to five other NEW MATTER rejections (Issue Nos. 2, 4, 6, 8 and 9), we would like to discuss the basis of support in the specification.

6. We would also like to discuss separately the patentability of claims 3284, 3285 and 3286, which are directed to "[a] non-porous solid support comprising nucleic acid directly fixed or directly immobilized thereto in hybridizable form" (claim 3284); "[a] non-porous solid support comprising a nucleic acid directly fixed or directly immobilized thereto in hybridizable form" (claim 3285); and "[a] non-porous solid support comprising DNA or RNA directly fixed or directly immobilized thereto in hybridizable form" (claim 3286).

7. On the anticipation rejection, we will discuss evidence showing that Stuart's '847 patent is limited in its disclosure to *in situ* hybridization using fixed cells, or as an alternative, colony hybridization on porous surfaces such as filter paper or diazotized paper. Unlike Stuart's disclosure, the pending '070 claims require a non-porous solid support and disclaim *in situ* hybridization.

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Enz-7(P)(C3)

PROPOSED AGENDA FOR DECEMBER 16, 2004 INTERVIEW

U.S. PATENT APPLICATION SERIAL NO. 08/479,997

1. Purpose of the interview is to reduce or resolve the remaining issues and/or to place the application in allowable condition.
2. Summary of rejections in the November 29, 2004 Advisory Action:

| ISSUE NO. | REJECTION | DESCRIPTION |
|-----------|--|--|
| 1 | NEWMATTER & VAGUE/INDEFINITE | [Sig] "comprising at least three carbon atoms" |
| 2 | NEWMATTER & VAGUE/INDEFINITE | "or modified nucleotide analog" |
| 3 | NEWMATTER /REQUIRING FURTHER CONSID. AND/OR SEARCH | improper amending status identifiers |
| 4 | DOES NOT PLACE APPLIC. IN ALLOW. CONDITION | [Sig comprising] "non-nucleotidyl" |
| 5 | VAGUE/INDEFINITE | "deoxy-type oligomers or polydeoxyribonucleotides" |
| 6 | ENABLEMENT | "furanosyl" |
| 7 | ANTICIPATION | Hartman et al. <u>Biopolymers</u> (1981) |

3. Of the 7 rejections listed above, claim proposals were made or will be presented for five of the issues (Nos. 1, 2, 4, 5 and 6) as follows:

ISSUE 1: [Sig] "**comprising at least three carbon atoms**" (**bold**).

ISSUE 2: "**or modified nucleotide analog**" (**bold & underlined**)

ISSUE 4: [**Sig comprising**] "**non-nucleotidyl**" (**underlined & italicized**)

Claim 826. An oligo- or polydeoxyribonucleotide which is complementary to a nucleic acid of interest or a portion thereof, said oligo- or polydeoxyribonucleotide comprising at least one modified nucleotide or modified nucleotide analog having the formula

Sig—PM—SM—BASE

wherein PM is a phosphate moiety, SM is a furanosyl moiety and BASE is a base moiety or a base analog comprising a pyrimidine, a pyrimidine analog, a purine, a purine analog, a deazapurine or a deazapurine analog, wherein said analog can be attached to or coupled to or incorporated into DNA or RNA, wherein said analog does not substantially interfere with double helix formation or nucleic acid hybridization, wherein said PM is attached to SM, said BASE is attached to SM, said Sig is covalently attached to PM directly or through a chemical linkage, and wherein said Sig **comprises at least three carbon atoms and comprises a non-polypeptide**,

non-nucleotidyl, non-radioactive label moiety which **Sig** can be directly or indirectly detected when attached to PM or when said modified nucleotide **or modified nucleotide analog** is incorporated into said oligo- or polydeoxyribonucleotide or when said oligo- or polydeoxyribonucleotide is hybridized to said complementary nucleic acid of interest or a portion thereof.

Enz-5(D6)(C2)

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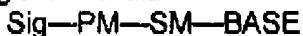
4. On the issue of Sig comprising a *non-nucleotidyl* label moiety, we would also like to discuss the Supplemental Declaration of Dr. Alex A. Waldrop, III, who concludes at the top of page 6 that "the '997 specification reasonably conveys that the Sig component is non-nucleotidyl." Supporting reasons for Dr. Waldrop's conclusion are found on pages 6-12 of his Declaration.

ISSUE 5: "deoxy-type oligomers or polydeoxyribonucleotides".

855. An oligo- or polynucleotide comprising the The oligo- or polydeoxyribonucleotide of claim 826, and further comprising at least one ribonucleotide.

ISSUE 6: "furanosyl" (bold**)**

956. An oligo- or polynucleotide which is complementary to a nucleic acid of interest or a portion thereof, said oligo- or polynucleotide comprising at least one modified nucleotide or modified nucleotide analog having the formula



wherein PM is a phosphate moiety, SM is a sugar furanosyl moiety and BASE is a base moiety comprising a pyrimidine, a pyrimidine analog, a purine, a purine analog, a deazapurine or a deazapurine analog wherein said analog can be attached to or coupled to or incorporated into DNA or RNA wherein said analog does not substantially interfere with double helix formation or nucleic acid hybridization, said PM being attached to SM, said BASE being attached to SM, and said Sig being covalently attached to PM directly or through a chemical linkage, and wherein said Sig comprises a non-polypeptide, non-nucleotidyl, non-radioactive label moiety comprising at least three carbon atoms and which Sig can be directly or indirectly detected when attached to PM or when said modified nucleotide or modified nucleotide analog is incorporated into said oligo- or polynucleotide or when said oligo- or polynucleotide is hybridized to said complementary nucleic acid of interest or a portion thereof, and wherein Sig comprises biotin, iminobiotin, an electron dense component, a magnetic component, a metal-containing component, a fluorescent component, a chemiluminescent component, a chromogenic component, a saccharide component or a combination of any of the foregoing.

5. Of the two remaining issues (Nos. 3 and 7), the former requires no claim amendments other than a clean set of claims with the proper claim amending status identifiers. The latter (No. 7) is a prior art rejection for anticipation that would be overcome upon withdrawing the NEW MATTER rejection based on the recitation of the term "non-nucleotidyl" in the pending claims.

Enz-5(D6)(C2)